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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,427	07/19/2001	James Aitken	5017-8122	9777
21888	7590	06/30/2005	EXAMINER	
THOMPSON COBURN, LLP ONE US BANK PLAZA SUITE 3500 ST LOUIS, MO 63101			CROSS, LATOYA I	
		ART UNIT	PAPER NUMBER	
			1743	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/909,427	AITKEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 April 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-6,9-16 and 18-20 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-6,9-16 and 18-20 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 05 August 2004 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

This Office Action is in response to Applicants' remarks filed on April 6, 2005.

Claims 1-6, 9-16 and 18-20 are pending.

### ***Terminal Disclaimer***

The terminal disclaimer filed on April 6, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on 09/943,647 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-6, 12, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,660,791 to Brenneman et al in view of Friedlander et al.

Brenneman et al disclose a sensor dispensing instrument for dispensing sensors to detect glucose in blood. The dispenser has a sensor pack loaded therein, wherein the sensor pack contains a plurality of testing elements (34). The dispensing instrument has an outer housing (36) and also has a slide actuator (42) in the housing that is manually slid from a standby position to a testing position to place the sensor in a data processing

or display mode (similar to Applicants' pusher and actuation member). The movement of the slide actuator toward the testing position forces the blade (50) of a blade assembly (48) to pierce a portion of the foil (52) that serves a seal over each of the sensor cavities.

After the sensor has been ejected from the sensor cavity, the sensor is in its testing position. Electrical contacts (58) on the sensor are coupled with electronic circuitry (not shown) in the housing. The circuitry may include a microprocessor. After testing, the spent sensor is released from the housing and the slide actuator is manually retracted back to its standby position.

Brenneman et al differ from the instantly claimed invention in that the testing elements of Brenneman et al are disposed in circularly shaped base, not in a stack as recited in claim 1. further, there is no disclosure of a spring urging the testing elements toward the seal.

Friedlander et al teach sensor assembly wherein a plurality of sensors is arranged in a stacked relation inside a tubular magazine. A spring (5) urges each of the sensors upwardly. See figure 3. It would have been obvious to one of ordinary skill in the art to modify Brenneman et al to have the sensors arranged in a stack to allow more testing elements to be disposed in the housing since the spatial drawbacks of the circular disc are alleviated.

3. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al and Friedlander et al and further in view of US Patent 4,279,861 to Jessop.

The disclosures of Brenneman et al and Friedlander et al are described above.

Neither reference has any disclosure of a ratchet wheel.

Jessop teaches a cartridge for containing test elements for use in performing biological analyses. In moving the test elements out of the cartridge, Jessop teaches using a ratchet wheel as a means for preventing the test elements from moving backwards into the cartridge (i.e. as an anti-backup means). See col. 5, lines 28-51. It would have been obvious to one of ordinary skill in the art to include a ratchet wheel in the device of Brenneman et al to prevent the test elements from accidentally being moved backwards into the magazines.

4. Claims 11, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al and Friedlander et al in view of US Patent 6,534,017 to Bottwein et al.

The disclosures of Brenneman et al and Friedlander et al are described above.

Neither reference contains disclosure of a sliding member and no disclosure of the physical description of the test elements to be used.

Bottwein et al teaches a test element storage device comprising a magazine having stacked test elements disposed therein. With respect to claim 11, Bottwein et al teaches using a slide mechanism that serves to remove test elements. The slide is moved incrementally by a length corresponding to the width of the test element. Bottwein et al teaches that the slide can be coupled to a rod, wherein rotation of the rod causes a thrust of the slide and movement of the test elements (col. 6, lines 1-51). It would have been obvious to one of ordinary skill in the art to use a slide mechanism in conjunction with pusher of Brenneman et al to allow the movement of the test elements to be driven by a control unit in an automated manner, where the slide and pusher are both operated by drive units.

With respect to claims 18 and 19, Bottwein et al teaches using testing elements having test zones covered on a portion of the test element. In figure 1B of Bottwein et al, the test elements are shown having test zones (3) on a support (2). The thickness of the test zone (working area) is greater than the thickness of the non-test zones (non-working area). These testing elements are conventionally used in the analytical testing field and it would have been obvious to one of ordinary skill in the art to use such testing elements in the device of Brenneman et al.

*Response to Arguments*

5. Applicant's arguments filed April 6, 2005 have been fully considered but they are not persuasive. With respect to the obviousness rejection over Brenneman et al in view of Friedlander et al, Applicants argue that there no teaching of 1) the test elements being sealed and 2) there is no movement of the magazine relative to the housing.

In response, the Examiner would like to point out that in Brenneman et al, the reference teaches a foil seal (52), which does not cover individual test elements. Instead, the foil seal serves as a cover for all the test elements. See figure 5 where the foil seal (52) is a large wrap that covers the entire test pack.

With respect to the magazine moving in relation to the housing, Brenneman et al show at figure 9 the movement of the test elements within the housing (the elements being present in a magazine). Such movement corresponds with the manner in which the device operates – a test element is moved to the testing location. Once that test has been performed, the next element moves into the testing location. Thus, the testing elements in the magazine do move in relation to the housing.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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